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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/064,000	04/21/1998	JAMES P. ELIA	796-P-12	5311

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EXAMINER
KEMMERER, ELIZABETH

ART UNIT	PAPER NUMBER
1646	21

DATE MAILED: 09/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/064,000	ELIA, JAMES P.	
	Examiner	Art Unit	
	Elizabeth C. Kemmerer, Ph.D.	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 March 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-191* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *7-191* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Advisory Information

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1646, Examiner Elizabeth C. Kemmerer, Ph.D.

The suspension of prosecution (Paper No. 18, 16 November 2001) is terminated. Prosecution is open.

Election/Restrictions

PART I – RESTRICTION INTO GROUPS

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 7-14, 26, 27, 29-76, 88, 89, 91-137, 149, 150, 152-191 (in part), drawn to a method for producing a desired soft tissue in a body of a human patient comprising administering a growth factor which is a bacterium, classified in class 424, subclass 234.1.

II. Claims 7-14, 28-76, 90-137, 151-191 (in part), drawn to a method for producing a desired soft tissue in a body of a human patient comprising administering a growth factor which is a virus, classified in class 424, subclass 204.1, for example.

III. Claims 7-11, 15, 29-73, 77, 91-134, 138, 152-191 (in part), drawn to a method for producing a desired soft tissue in a body of a human patient comprising administering a growth factor which is a PDGF protein, classified in class 514, subclass 2.

IV. Claims 7-11, 15, 29-73, 77, 91-134, 138, 152-191 (in part), drawn to a method for producing a desired soft tissue in a body of a human patient comprising administering a growth factor which is a PDGF gene, classified in class 514, subclass 44.

V. Claims 7-11, 16, 29-73, 78, 91-134, 139, 152-191 (in part), drawn to a method for producing a desired soft tissue in a body of a human patient comprising administering a growth factor which is an EGF protein, classified in class 514, subclass 2.

VI. Claims 7-11, 16, 29-73, 78, 91-134, 139, 152-191 (in part), drawn to a method for producing a desired soft tissue in a body of a human patient comprising administering a growth factor which is an EGF gene, classified in class 514, subclass 44.

VII. Claims 7-11, 17, 29-73, 79, 91-134, 140, 152-191 (in part), drawn to a method for producing a desired soft tissue in a body of a human patient comprising administering a growth factor which is an FGFa protein, classified in class 514, subclass 2.

VIII. Claims 7-11, 17, 29-73, 79, 91-134, 140, 152-191 (in part), drawn to a method for producing a desired soft tissue in a body of a human patient comprising administering a growth factor which is an FGFa gene, classified in class 514, subclass 44.

IX. Claims 7-11, 17, 29-73, 79, 91-134, 140, 152-191 (in part), drawn to a method for producing a desired soft tissue in a body of a human patient

comprising administering a growth factor which is an FGFb protein, classified in class 514, subclass 2.

X. Claims 7-11, 17, 29-73, 79, 91-134, 140, 152-191 (in part), drawn to a method for producing a desired soft tissue in a body of a human patient comprising administering a growth factor which is an FGFb gene, classified in class 514, subclass 44.

XI. Claims 7-11, 18, 29-73, 80, 91-134, 141, 152-191 (in part), drawn to a method for producing a desired soft tissue in a body of a human patient comprising administering a growth factor which is an interleukin protein, classified in class 424, subclass 85.2.

XII. Claims 7-11, 18, 29-73, 80, 91-134, 141, 152-191 (in part), drawn to a method for producing a desired soft tissue in a body of a human patient comprising administering a growth factor which is an interleukin gene, classified in class 514, subclass 44.

XIII. Claims 7-11, 19, 29-73, 81, 91-134, 142, 152-191 (in part), drawn to a method for producing a desired soft tissue in a body of a human patient comprising administering a growth factor which is a TNF protein, classified in class 514, subclass 2.

XIV. Claims 7-11, 19, 29-73, 81, 91-134, 142, 152-191 (in part), drawn to a method for producing a desired soft tissue in a body of a human patient comprising administering a growth factor which is a TNF gene, classified in class 514, subclass 44.

XV. Claims 7-11, 20, 29-73, 82, 91-134, 143, 152-191 (in part), drawn to a method for producing a desired soft tissue in a body of a human patient comprising administering a growth factor which is a TGF protein, classified in class 514, subclass 2.

XVI. Claims 7-11, 20, 29-73, 82, 91-134, 143, 152-191 (in part), drawn to a method for producing a desired soft tissue in a body of a human patient comprising administering a growth factor which is a TGF gene, classified in class 514, subclass 44.

XVII. Claims 7-11, 21, 29-73, 83, 91-134, 144, 152-191 (in part), drawn to a method for producing a desired soft tissue in a body of a human patient comprising administering a growth factor which is a CSF protein, classified in class 514, subclass 2.

XVIII. Claims 7-11, 21, 29-73, 83, 91-134, 144, 152-191 (in part), drawn to a method for producing a desired soft tissue in a body of a human patient comprising administering a growth factor which is a CSF gene, classified in class 514, subclass 44.

XIX. Claims 7-11, 22, 29-73, 84, 91-134, 145, 152-191 (in part), drawn to a method for producing a desired soft tissue in a body of a human patient comprising administering a growth factor which is an osteopontin protein, classified in class 514, subclass 2.

XX. Claims 7-11, 22, 29-73, 84, 91-134, 145, 152-191 (in part), drawn to a method for producing a desired soft tissue in a body of a human patient

comprising administering a growth factor which is an osteopontin gene, classified in class 514, subclass 44.

XXI. Claims 7-11, 23, 29-73, 85, 91-134, 146, 152-191 (in part), drawn to a method for producing a desired soft tissue in a body of a human patient comprising administering a growth factor which is an interferon protein, classified in class 424, subclass 85.4.

XXII. Claims 7-11, 23, 29-73, 85, 91-134, 146, 152-191 (in part), drawn to a method for producing a desired soft tissue in a body of a human patient comprising administering a growth factor which is an interferon gene, classified in class 514, subclass 44.

XXIII. Claims 7-11, 24, 29-73, 86, 91-134, 147, 152-191 (in part), drawn to a method for producing a desired soft tissue in a body of a human patient comprising administering a growth factor which is a BMP-1 protein, classified in class 514, subclass 2.

XXIV. Claims 7-11, 24, 29-73, 86, 91-134, 147, 152-191 (in part), drawn to a method for producing a desired soft tissue in a body of a human patient comprising administering a growth factor which is a BMP-1 gene, classified in class 514, subclass 44.

XXV. Claims 7-11, 25, 29-73, 87, 91-134, 148, 152-191 (in part), drawn to a method for producing a desired soft tissue in a body of a human patient comprising administering a growth factor which is an IGF protein, classified in class 514, subclass 2.

XXVI. Claims 7-11, 25, 29-73, 87, 91-134, 148, 152-191 (in part), drawn to a method for producing a desired soft tissue in a body of a human patient comprising administering a growth factor which is an IGF gene, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons: Inventions I-XXVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together and have different modes of operation. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups I-XXVI are directed to methods that are distinct both physically and functionally, and are not required one for the other, and are therefore patentably distinct. Examination of the method of Group I requires search and consideration of bacteria therapy. Examination of the method of Group II requires search and consideration of virus therapy. Examination of the methods of Groups III, V, VII, IX, XI, XIII, XV, XVII, XIX, XXI, XXIII and XXV requires search and consideration of protein therapy. Examination of the methods of Groups IV, VI, VIII, X, XII, XIV, XVI, XVIII, XX, XXII, XXIV and XXVI requires search and consideration of gene therapy. Each type of

method involves very different method steps, and the agents being administered have very different biochemical and biological properties. For example, a reference describing administration of a polypeptide growth factor does not anticipate, nor necessarily render obvious, a claim to administration of a gene encoding that polypeptide growth factor. The searches required for the three methods are non-overlapping, resulting in a search burden. Regarding the different protein therapies of Groups III, V, VII, IX, XI, XIII, XV, XVII, XIX, XXI, XXIII and XXV, a search for one growth factor protein would not necessarily reveal any useful information regarding another growth factor protein. Each protein would have to be searched separately by name and sequence. Clearly, search and examination of all of the different growth factor proteins in one application would result in an undue search burden. Similarly, regarding the different gene therapies of Groups IV, VI, VIII, X, XII, XIV, XVI, XVIII, XX, XXII, XXIV and XXVI, a search for one growth factor gene would not necessarily reveal any useful information regarding another growth factor gene. Each gene would have to be searched separately by name and sequence. Clearly, search and examination of all of the different growth factor genes in one application would result in an undue search burden. Therefore, a search and examination of all of the methods in one patent application would result in an undue burden, since the searches for the methods are not co-extensive, the classification is different, and the subject matter is divergent.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject

matter, separate search requirements, and different classification, restriction for examination purposes as indicated is proper.

PART II – SPECIES REQUIREMENT REGARDING CARRIER

This application contains claims directed to the following patentably distinct species of the claimed invention:

II-a) the carrier controls cell growth;

II-b) the carrier controls cell migration;

II-c) the carrier controls cell function;

II-d) the carrier is resorbable;

II-e) the carrier is non-resorbable;

II-f) the carrier comprises a gel;

II-g) the carrier comprises a time-release capsule;

II-h) the carrier comprises a granule;

II-i) the carrier is activated by tissue pH to release the growth factor;

II-j) the carrier is activated by an enzyme to release the growth factor;

II-k) the carrier is activated by ultrasound to release the growth factor;

II-l) the carrier is activated by electricity to release the growth factor;

II-m) the carrier is activated by heat to release the growth factor;

II-n) the carrier is activated by an in vivo chemical to release the growth factor.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 7 is an example of a generic claim.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

PART III – SPECIES REQUIREMENT REGARDING GROWTH FACTOR

This application contains claims directed to the following patentably distinct species of the claimed invention:

III-a) the growth factor is activated by tissue pH;

III-b) the growth factor is activated by an enzyme;

III-c) the growth factor is activated by ultrasound;

III-d) the growth factor is activated by electricity;

III-e) the growth factor is activated by heat;

III-f) the growth factor is activated by an in vivo chemical.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 7 is an example of a generic claim.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention **(ONE FROM PART I, ONE FROM PART II, AND ONE FROM PART III)** to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D. whose telephone number is (703) 308-2673. The examiner can normally be reached on Monday through Thursday, 6:30 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne L. Eyler, Ph.D. can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER

ECK